# 510(k) Summary:

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: B-K Medical A/S

Address: Sandtoften9, DK2820Gentofte, Denmark

Phone: +45 45970100 Fax: +45 45970199

Contact person: Villy Braender, Quality Assurance Mnager

Date prepared: 5.July, 2000

Trade name: Ultrasound Scanner Type 1101 Common name: Diagnostic Ultrasound System

Classification names:

Ultrasonic Pulsed Echo Imaging System (90 IYO, CFR 892.1560)

Diagnostic Ultrasonic Transducer

(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed device: B-K Medical A/S 2002 Ultrasound Scanner (K943315)

# **Device description:**

1101 supports the following scanning modes and combinations thereof:

B-mode M-mode.

The system can perform simple geometric measurements, and perform calculations in the areas of Vascular, Urology, Cardiology and OB/GYN applications.

The system can guide biopsy- and puncture needles.

#### <u>Transducers</u>

Transducers are linear and convex array and mechanical sector.

The patient contact materials comply with ISO10993-1

All transducers used together with 1101 are Track 3 transducers.

#### Acoustic output

The system controlling the Acoustic Output in 1101 is the same as the system in 2002. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta  $\leq 720 \text{ mW/cm}^2$  and MI  $\leq 1.9$  (Track 3, non ophthalmic).

The Thermal Index values are maximum 6.0, i.e.  $TI \le 6.0$ 

# Clinical measurement accuracy.

Clinical measurements and calculations are described and accuracies are provided in the User Guide.

# Thermal, mechanical and electrical safety.

The scanner 1101 is tested by a recognized, certified body according to IEC 60601-1.

## Acoustic Output Reporting

The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 30, 1997"

The acoustic output is measured and calculated according to: "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment" (NEMA 1997).

#### Intended use.

1101 intended uses are contained within 2002-intended uses:

	Predicate device,	Submitted device,
	Ultrasound scanner Type 2002 (K943315)	Ultrasound scanner Type
·		1101
Modes of operation	B, M, PWD, CFM and combinations	B, M and combinations
Intended use(clinical	Abdominal	Abdominal
application)	Cardiac	Cardiac
	Fetal Doppler	Fetal
	Intraoperative	Intraoperative
	Neurosurgery	Neurosurgery
	Obstetrics	Obstetrics
	Pediatrics	Pediatrics
	Transrectal	Transrectal
	Small Parts (organs)	Small Parts (organs)
	Transvaginal	Transvaginal
·	Peripheral vascular	

# Technological characteristics compared to the predicate device.

The predicate device has the same major technological characteristics as the subject device described above.

Minor differences consist: The subject device has modified transmitter, increased beamformer delay accuracy, increased storage capability and modified user interface and mechanical outline.



AUG 1 2000

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Villy Braender Official Correspondent B-K Medical Sandtoften 9 DK 2820 Gentofte, Denmark

Re:

K002085

Ultrasound Scanner Type 1101

Regulatory Class: II

21CFR 892.1560/Procode: 90 IYO 21CFR 892.1570/Procode: 90 ITX

Dated: July 5, 2000 Received: July 10, 2000

#### Dear Mr. Braender:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Ultrasound Scanner Type 1101, as described in your premarket notification:

#### Transducer Model Number

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration Center for Devices and Radiological Health Document Mail Center (HFZ-401) 9200 Corporate Boulevard Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

Daniel G. Schultz, M.D.

Captain, USPHS

Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation Center for Devices and

Radiological Health

**Enclosures** 

# Diagnostic Ultrasound Indications for Use Form

System: 1101

# Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

						Mode	of Operation			
Clinical Application	Α	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic					ļ					
Fetal		X	X	ļ <u> </u>	ļ				X (B+M)	
Abdominal		Х	Х				·		X (B+M)	
Intraoperative (specify)		X	×	ļ					X (B+M)	70.0
Intraoperative Neurological		х	X						X (B+M)	
Pediatric		x	х		ļ				X (B+M)	
Small Organ (specify)		х	Х						X (B+M)	
Neonatal Cephalic									لا على الم تحريض علا كان مناب	
Adult Cephalic										
Cardiac		Х	X				· .	1 President is	X (B+M)	1.12
Transesophageal									, fora e e	
Transrectal		x	X			<u> </u>			"X (B+M)	
Transvaginal		X	X						X (B+M)	
Transurethral										
Intravascular									e e de de descento dos	
Peripheral Vascular			<u> </u>					-		
Laparoscopic								2.7.76	12,000 to 12,000	
Musculo-skeletal								ري د او درون د يوني درون د او درون د يوني		
Conventional		1	1							
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Additional Comments:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K00 J085

CI	inical Application				Mod	le of Operat	ion	
General	Specific	В	М	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks   & III)	1				Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic							
	Fetal							
	Abdominal							•
	Intra-operative (Specify)	P					., ca 6	
	Intra-operative (Neuro)							·····
	Laparoscopic						, compare	· · · · · · · · · · · · · · · · · · ·
Fetal Imaging	Pediatric	1						- "
& Other	Small Organ (Specify)					7,657 <b>0478</b>	i jari karistan Kalendari	3.
	Neonatal Cephalic	1						
	Adult Cephalic					77 (1574) 1116		
	Trans-rectal	P						
	Trans-vaginal							
	Trans-urethral							·
	Trans-esoph. (non-Card.)					symbolis	· · · · · · · · · · · · · · · · · · ·	
	Musculo-skel. (Conventional)					***		
	Musculo-skel. (Superficial)							
	Intra-luminal						and the same	- 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
	Other (Specify)							
	Cardiac Adult						And the second second second	
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)					i e styrouensten sida	i i i i i i i i i i i i i i i i i i i	1. 1. 2. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.
	Other (Specify)	· ·						
Peripheral	Peripheral vessel					e garanta a ayesta	1 14,75,744	
Vessel	Other (Specify)				<del></del>		,	
*Examples may Color Velocity In	ion; P= previously cleared by FD include: A-mode, Amplitude Do maging ments: Intraoperative: Rectum, U	ppler,	3-D	Imaging,	Harmon			Doppler,
Additional Com	ments: Intraoperative: Rectum, U	Irethr	a, Ur	inary bla	dder,		·	
		·····						

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number

	linical Application				Mod	le of Opera	tion	,
General (Track I Only)	Specific (Tracks I & III)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify
Ophthalmic	Ophthalmic							Среси
	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)					, , , , , , , , , , , , , , , , , , ,		*
	Laparoscopic						- I	
Fetal Imaging	Pediatric							
& Other	Small Organ (Specify)					·r		
	Neonatal Cephalic							
	Adult Cephalic				-	<del></del>		
	Trans-rectal							<del></del>
	Trans-vaginal	1				to electrical departments	en a de la companya	
	Trans-urethral							
	Trans-esoph. (non-Card.)					1850 1850 F		The second second
	Musculo-skel. (Conventional)			****				
	Musculo-skel. (Superficial)							
	Intra-luminal					1.		
	Other (Specify)							
	Cardiac Adult	Р	P			e de la serie de la	P (B+M)	
Cardiac	Cardiac Pediatric						. (0)	
	Trans-esoph. (Cardiac)					e e esan		
	Other (Specify)							
Peripheral	Peripheral vessel					a a the spirit, and a superment	and the same of the	The second second
Vessel	Other (Specify)					4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Company of the Commission	
N = new indicati *Examples may i Color Velocity In	on; P = previously cleared by FE include: A-mode, Amplitude Do naging	A(K9 ppler,	94331 3-D	(5); E= Imaging,	added ur Harmoni	ider Append c Imaging, 7	fix E Tissue Motion I	Doppler,

Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number <u>KOO 2085</u>

System:	1101									
Transducer:	8560									
	Diagnostic ultrasound imaging or	fluid	flow a	malysis o						
CI	inical Application	Mode of Operation								
General	Specific	B	M	PWD	CWD	Color	Combined	Other*		
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify		
Ophthalmic	Ophthalmic	ļ								
	Fetal	ļ	ļ		<u> </u>					
	Abdominal		<u> </u>							
	Intra-operative (Specify)	E	E				E (B+M)			
	Intra-operative (Neuro)					ļ	<u> </u>			
	Laparoscopic									
Fetal Imaging	Pediatric	E	E				E (B+M)			
& Other	Small Organ (Specify)	E	E			1.387	E (B+M)			
	Neonatal Cephalic					5. 60% C \$9.1 ().	100	4,41.5		
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal					i in the large Manager of the states are Manager	amented Asia and a process a seeks 成園 an eest	en de la companya de La companya de la co		
	Trans-urethral									
	Trans-esoph. (non-Card.)					in the paster of the	estado pero estado en carros			
	Musculo-skel. (Conventional)									
	Musculo-skel. (Superficial)					a the processing	19 10 10 10 10 10 10 10 10 10 10 10 10 10	100		
	Intra-luminal									
	Other (Specify)					and an income to	the section of the section of the section of	,		
	Cardiac Adult					este projection and an	g State Section 1			
Cardiac	Cardiac Pediatric									
	Trans-esoph. (Cardiac)	1				. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.				
	Other (Specify)									
Peripheral	Peripheral vessel	1				1. J. C. 1. (1. 2. 2. 2. 2. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1.				
Vessel	Other (Specify)									
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N = new indication; P = previously cleared by FDA; E = added (K943315) under Appendix E

ditional Comments	: Intraoperative: Breast, liver, pancreas, biliary system
	Small Organ: Breast, testis, penis, thyroid, parathyroid, salivary glands, lymph nodes
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Concurrence of Center for Devices and Radiological Health, Office of Device Evaluation

Prescription Use (Per 21 QFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K062085

<sup>\*</sup>Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging

Transducer:	8561							
riansaucer.	0501		_					
Intended Use: [	Diagnostic ultrasound imaging or	fluid	flow a	nalysis o	f the hum	ian body as	follows:	
	inical Application	T				le of Opera		
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic						(0,000.7)	(opecii)/
	Fetal	E	E				E (B+M)	
	Abdominal						, , ,	
	Intra-operative (Specify)							
•	Intra-operative (Neuro)							
	Laparoscopic							
Fetal Imaging	Pediatric							
& Other	Small Organ (Specify)							
	Neonatal Cephalic	1						******
	Adult Cephalic						1000	
	Trans-rectal	E	E				E (B+M)	<del></del>
	Trans-vaginal	E	E		M	n dan <sub>da</sub> n kan merapa Nga	E (B+M)	
	Trans-urethral							
	Trans-esoph. (non-Card.)				* (a*			
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)				.204	and the entire pages where	- 20	<del></del>
	Intra-luminal							<del> </del>
	Other (Specify)	1						
	Cardiac Adult					Active of Park		
Cardiac	Cardiac Pediatric	1						
	Trans-esoph. (Cardiac)	ļ				1 11 1 1874	0.048	
	Other (Specify)	1						
Peripheral	Peripheral vessel				V.a	n in despes		***************************************
Vessel	Other (Specify)							······································
N= new indicati	on; P = previously cleared by FD	A · F	= add	led (KQ4	3315) ni	nder Anner	div E	
*Examples may i	nclude: A-mode, Amplitude Do	ppler.	3-D	lmaging.	Harmoni	c Imaging. 1	Tissue Motion I	Donnier
Color Velocity Ir	naging	,	•			~agg,	113546 1 104011 1	soppici,
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Additional Comm	nents:							*
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

System:	1101					•		·
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			_					
	Diagnostic ultrasound imaging or	fluid	flow a	nalysis o				
	inical Application		T	I		le of Operat		<del></del>
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
(Track I Only)	(Tracks I & III)	<del> </del>	<del> </del>			Doppler	(Specify)	(Specify)
Ophthalmic	Ophthalmic	ļ	<b> </b>					
	Fetal	ļ	<del> </del>					
	Abdominal	-	<del>│                                    </del>				F /D . M()	
		E	E				E(B+M)	· · · · · · · · · · · · · · · · · · ·
		ļ	+				F (D . M)	
	Intra-operative (Specify) E E E E E (B+M)  Intra-operative (Neuro) E E E E (B+M)  Laparoscopic  Pediatric E E E E (B+M)  Small Organ (Specify)  Neonatal Cephalic  Adult Cephalic  Trans-rectal  Trans-vaginal  Trans-urethral  Trans-urethral  Trans-esoph. (non-Card.)  Musculo-skel. (Conventional)  Musculo-skel. (Superficial)  Intra-luminal  Other (Specify)  Cardiac Adult  Cardiac Pediatric							
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Fetal Imaging & Other  Small Organ (Specify)  Neonatal Cephalic  Adult Cephalic  Trans-rectal  Trans-vaginal  Trans-urethral  Trans-esoph. (non-Card.)  Musculo-skel. (Conventional)  Intra-luminal  Other (Specify)  Cardiac Adult  Cardiac Pediatric  Trans-esoph. (Cardiac)  Other (Specify)  Peripheral  Peripheral Peripheral vessel								
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	Other (Specify)							
Peripheral	Peripheral vessel	<u> </u>	<u> </u>		,			
Vessel	Other (Specify)							
N = new indicat	ion; P = previously cleared by FI	A; E	= ad	ded (K9	43315) ι	ınder Appei	ndix E	
*Examples may	include: A-mode, Amplitude Do	ppler	, 3-D	Imaging,	Harmon	ic Imaging,	Tissue Motion	Doppler,
Color Velocity I	maging							
Additional Com	ments:Intraoperative: Gall bla	dder_		<b>-</b>				
etrat per a transaction of the second								
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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number 600 5085

510(k) Number \_\_\_

	nical Application				Mod	le of Opera	tion	
General	Specific	В	M	PWD	CWD	Color	Combined	Other*
Track I Only)	(Tracks I & III)					Doppler	(Specify)	(Specify
Ophthalmic	Ophthalmic							
	Fetal	E	E				E (B+M)	
	Abdominal	E	E				E (B+M)	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
etal Imaging	Pediatric							
& Other	Small Organ (Specify) Neonatal Cephalic Adult Cephalic Trans-rectal Trans-vaginal Trans-urethral Trans-esoph. (non-Card.)							
<b>4</b> 1 - 111 - 1		E E E E (B+M) (Specify) (Neuro)  pecify) alic  conventional) Superficial)  ic Cardiac)						
		1						
	Trans-rectal							
					·			
	Trans-urethral							
	Musculo-skel. (Conventional)	1						
	Musculo-skel. (Superficial)							
	Intra-luminal		1					
•	Other (Specify)							
	Cardiac Adult						1.44	
Cardiac	Cardiac Pediatric							
	Trans-esoph. (Cardiac)						1.	
	Other (Specify)							
Peripheral	Peripheral vessel							
Vessel	Other (Specify)		1					
N= new indicati Examples may Color Velocity I	ion; P = previously cleared by Fl include: A-mode, Amplitude Do maging ments:	OA; E oppler	= add , 3-D	ded (K9 Imaging	43315) ι , Harmon	inder Appe ic Imaging,	ndix E Tissue Motion	Doppler,

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number 6003085